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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,224	07/21/2005	Volker Sandig	04156.0012U1	1743

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EXAMINER	
BARNHART, LORA ELIZABETH	
ART UNIT	**PAPER NUMBER**
1651	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,224	SANDIG ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 18-53 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 18-53 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 18-53, which were submitted in a preliminary amendment with the application, are currently pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 18-50, drawn to a process for preparing a cell capable of stable high-yield expression of a target gene product, the product of the process, and a method of using the product.

Group II, claim(s) 52 and 53, drawn to a protein.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: They lack inventive unity as directed by 37 C.F.R. 1.475.

An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) a product and a process specially adapted for the manufacture of said product; (2) a product and a process of use of said product; (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; (4) a process and an apparatus or means specifically designed for carrying out the said process; or (5) a product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. **If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims.** See 37 C.F.R. 1.475.

In this case, the first named product (i.e., the cell of claims 43-50), the first named process of use of said product (i.e., the method of claim 53), and the first named process specially adapted for the manufacture of said product (i.e., the process of claims 18-42) will be considered as the main invention; this situation is similar to that in category (3) above.

The product of Group II is a protein, which is a different product than the cell of Group I. Therefore, this Group is a distinct invention.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Manner of inserting DNA coding for the target gene product: (a) replacing the gene coding for the Ig with a first functional sequence containing one or more RRSs and then integrating a second functional DNA sequence comprising a DNA sequence that codes for the target gene product into the functionalized precursor cell by use of a recombinase recognizing the RRSs and (b) directly replacing the gene coding for the Ig with a DNA sequence that codes for the target gene product, as in claim 18; elect ONE if Group I is elected. Claims 30-38 and 40-42 will be examined to the extent they are commensurate in scope with this species election, e.g. if (a) is elected, claims 41 and 42 will be withdrawn.

Starting cells: (c) human myeloma, (d) human hybridoma, and (e) human hetero-hybridoma, as in claim 22; elect ONE if Group I is elected. Claim 23 will be examined to the extent that it is commensurate in scope with this election.

Sites of integration of the functional DNA sequences: (f) at a rearranged Ig locus, (g) at a rearranged IgH locus, and (h) at a lambda locus, as in claims 24-26; elect ONE if Group I is elected.

Methods of identifying the Ig locus: (i) microarray expression analysis, (j) 2D protein gel electrophoresis, (k) quantitative PCR, (l) RNase protection, (m) northern blot, (n) ELISA, and (o) western blot, as in claim 28; elect ONE if Group I is elected.

RRSs: (q) loxP, (r) frt, (s) attL and attR sites of lambdoid phages, (t) recognition site for resolvases, (u) recognition site for phage C31 integrase, (v) modified loxP, and (w) modified frt, as in claims 32 and 34; elect ONE if Group I and species (a) are both elected. Claim 38 will be examined such that it is commensurate in scope with this election, i.e. if (q) or (v) is elected, the scope of claim 38 will be limited to "Cre", and if (r) or (w) is elected, the scope of claim 38 will be limited to "flp", etc.

Additional features of first functional DNA sequences: (x) marker sequences, (y) secretion proteins, (z) promoters, (a') enhancers, (b') splice signals, (c') polyadenylation signals, and (d') IRES elements, as in claim 35; elect ONE if Group I and species (a) are both elected.

Target gene products: (e') enzymes, (f') hormones, (g') cytokines, (h') receptors, (i') antibodies, (j') antibody fragments, (k') fusion proteins comprising enzymes, (l') fusion proteins comprising hormones, (m') fusion proteins comprising cytokines, (n') fusion proteins comprising receptors, (o') fusion proteins comprising antibodies, and (p') fusion proteins comprising antibody fragments, as in claim 39; elect ONE whether Group I or Group II is elected.

Features of second functional DNA sequences: (q') promoter sequences, (r') marker sequences, (s') splice donor and acceptor sequences, and (t') RRSs, as in claim 40; elect ONE if Group I and species (a) are both elected.

Applicant is required, in reply to this action, to elect a single species from each category above, as directed, to which the claims shall be restricted if no generic claim is finally held to be allowable. In other words, a single embodiment in which all variables are defined should be elected for initial examination on the merits. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 19-21, 27, 29, 45, 47, 50, and 51.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative Instructions, Annex B, Part 1(f)(I)(B)(2), the species are not art-recognized equivalents. When alternatives of chemical compounds are claimed, they shall be regarded as being of a similar nature where all alternatives have

a common property or activity, and either a significant structural element is shared by all of the alternatives, or all of the alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains. The words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the common property or activity. The structural element may be a single component or a combination of individual components linked together. The words "recognized class of chemical compounds" mean that there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention. In other words, each member could be substituted one for the other, with the expectation that the same intended result would be achieved.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart
Examiner/Partial Signatory Authority
Temporary Full Signatory Authority (as of 12/9/07).